ISO 9001, QMS and You

What is ISO 9001

- It is an industry quality standard
- It describes what we need for an effective quality management system

Why do I care?

- ISO/QMS is about ***YOU*** and “how” ***YOU*** do ***YOUR*** job!
- ISO/QMS is concerned about how ***YOUR*** job affects the quality of the product
- You are accountable only for what ***YOU*** are doing!

ISO 9001 In Brief

An ISO 9001 compliant organization has in place a quality management system that ensures quality is built into each of the processes throughout the organization. This requires that we must:

SAY IT! **Document what we say we are going to do**

DO IT! **Exactly as we said we would**

PROVE IT! **That we did what we said we would**

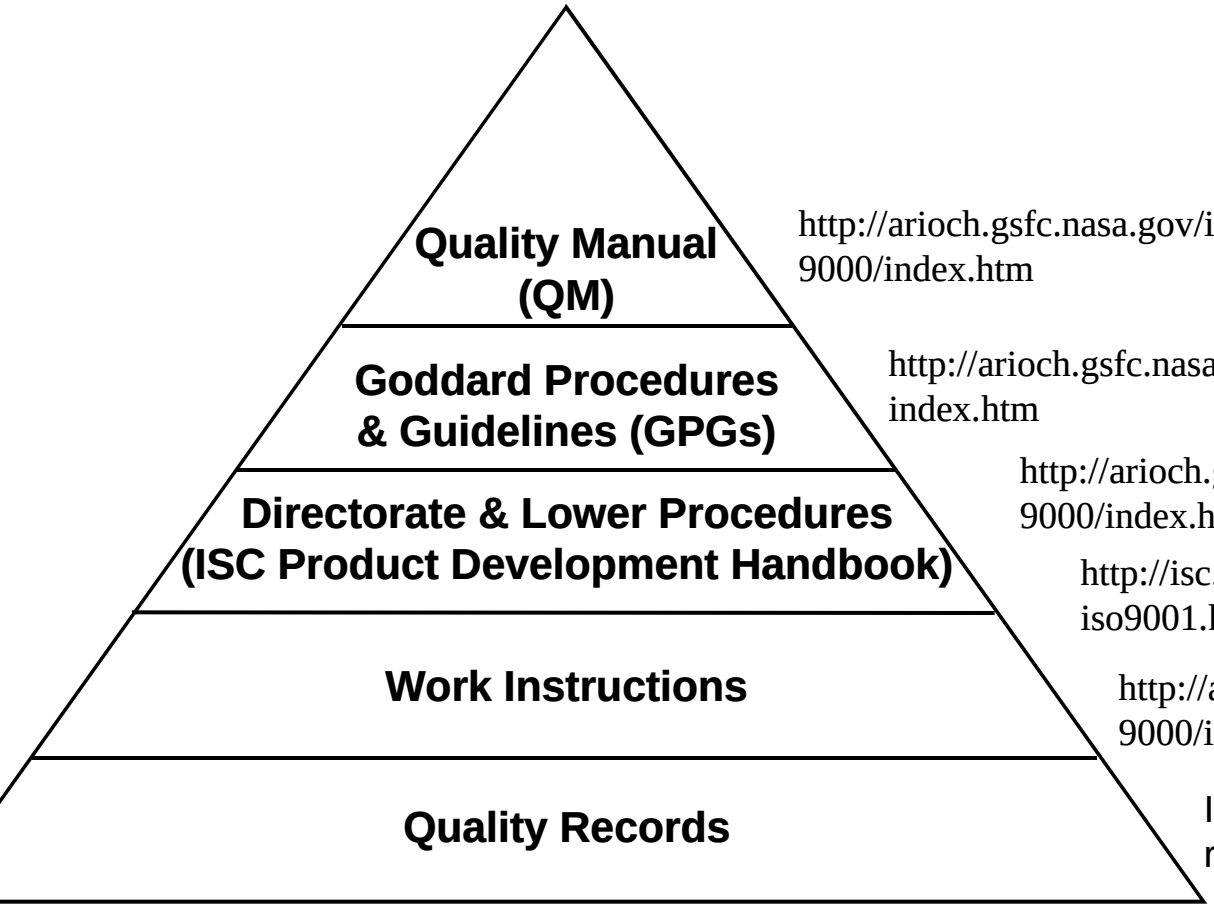
IMPROVE IT! **That we take every opportunity make our processes better**

What is the Quality Management System (QMS)

- It is the structure that implements ISO 9001 at GSFC
- It is a systematic approach to product quality improvement via process control throughout the organization
- It is described in a hierarchy of documentation that addresses the implementation of the 20 ISO elements

The Quality Management System

Document Hierarchy



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http://isc.gsfc.nasa.gov/iso9k/ iso9001.htm

http://arioch.gsfc.nasa.gov/iso 9000/index.htm

ISC Product Plan and qua records defined therein

How ISO 9001 Affects You

Product Life Cycle Activity	ISO 9001 Element
At some point you will receive an order for a product,	Contract Review
You need to design it,	Design Control
buy some of the parts,	Purchasing
maybe receive some of the parts from the customer,	Control of Customer-Supplied Prod
make some of the parts, and integrate the product.	Process Control
You need to be able to uniquely identify all of these components,	Product Identification and Traceabi
and test them,	Inspection and Test
against something.	Control of Inspection, Measuring, and Test Equipment
You need to keep track of the status of the product and components at all times with respect to requirements.	Inspection and Test Status
If you find a problem, you need to make sure you limit how it is used,	Control of Non-Conforming Materia
while you fix it, and find out how to keep the problem from reoccurring, if possible.	Corrective and Preventive Action, Statistical Techniques
Once you have validated the product, you need to deliver it,	Handling, Storage, Packaging, Preservation, and Delivery
and maintain it as agreed upon.	Servicing

What everyone must know!

- What the GSFC Quality Policy is (**With customer satisfaction as our primary goal :**
  - **GSFC is committed to meeting or exceeding our customer's requirements**
  - **We achieve excellence in all of our efforts)**
- What the Quality Policy means to you in performing your job
- What the Quality Manual is
- That our Product Plan is the ISO Quality Plan for the product

What everyone must know! (continued)

- How you are assigned work projects (by your supervisor) and where they are documented (in your performance plan)
- How you receive your work assignments within a project team (from the Team Lead, Project Manager, etc.)
- What products you are producing

What everyone must know! (continued)

- How you are qualified to do your job (education, training, OJT, etc.)
- What procedures define how you are to do your work
- What documents you use
- What Quality Records you need to keep to show that you followed procedures and what the results were

f you are: A Team Lead

- You ***MUST*** have a Product Plan!
- You must document the elements identified in the Project Plan (including Quality Records) as appropriate for your specific product (depending on type and complexity)

SC Product Plan Outline

-For Current ISC Product Plan Outline, Check ISC website:

http://isc.gsfc.nasa.gov/iso9k/iso9001.htm

Quality Record Types

List of Quality Record Types

The Quality Record Custodian is the Team Lead unless specified otherwise by the Product Pl
internal (to ISC) teams shall be maintained in the appropriate Branch for one year following
For flight projects, the quality records transition to the flight project at the delivery of the pro

Examples of Typical ISC Quality Record Types

Team Lessons Learned
ISC Metrics Collected
Employee Training Records (formal, other)
Required On-The Job Training Records
Product Plans for Internal ISC Teams (Will be numbered 58x-WI-8700.1.y, where x is last di
sequence number of document)

Examples of Typical Team Quality Record Types

Product Plan (including requirements)
Design Planning (in Product Plan)
Schedules (Must be part of design planning)
Budget (Must be part of design planning)
Process Management Plan (In Product Plan)

Quality Record Types (continued)

Process Management Plan (In Product Plan)
System/Peer Review Plans (In Product Plan)
System Review/Peer Review Packages
Requests for Action (RFA's) from Reviews and Responses)Peer Review Summary
Metrics Collected by the Team (includes product metrics, Team process metrics, and ISC pr
Team Lessons Learned
Interface Control Documents
Contractor Performance Surveys – NASA form NF 1680
Non-Conformance Reports for Simplified Acquisition (Form 210-1)
Customer Supplied Elements
Work Order Authorizations (WOA) Use On-Line System)
Procurement Requests
Receiving Inspection Instructions
Incoming Inspection Non-Conformance Reports
Design documents (peer review, prototype evaluation, code reading records, code walk-through record
Configuration Management Records
Product Releases
Product Documentation
NCRs and Disposition (NCR's that meet criteria in GPG 1710.1 need to be entered in

Quality Record Types (continued)

NCRs and Disposition (NCR's that meet criteria in GPG 1710.1 need to be entered in Center on-line database)
Corrective Action Plans
Preventive Action Action Item List
Test Verification and Validation Plans
Test Status
Test Verification and Validation Results
Log of Key Issues, Decisions, and Rationale
Shipping Records (Form 20-4)
Records of Verification of Test Software and Comparative References

If you are: A Team Member

- You need to know what parts of the Product Plan affect you

f you are: A Supervisor

- You need to be sure that employees training records in personnel are up to date with Center and non-Center sponsored training classes taken
- You need to identify training needs for employees, and that they receive it

f you are: A Supervisor continued)

- You need to ensure you assign qualified individuals to projects
- You must maintain internal Product Team Quality Records for 1 year following completion of product delivery

If you are: Purchasing Something (item or service)

- You must know what procurement procedures affect you
- You must specify the purchase requiremer
- You must specify your receiving inspection instructions
- You must provide inspection results
- You must provide feedback on subcontract satisfaction

For ALL of the prior information, YOU also must know:

- Where the information is documented
- Where the documentation can be found
- How the documentation is controlled
- How you know you have the latest version
- What Quality Records you are responsible for providing

Examples of Job Type Sensitivity to ISO Elements

	Job Types			
ISO 9001 Elements	Making	Analyzing / Planning	Leading	Moni
Management Responsibility				
Quality System	POLICY	POLICY	POLICY	PO
Contract Review			X	
Design Control	X	REVIEWS	X	
Document and Data Control	X	X	X	
Purchasing	MAYBE	MAYBE	X	MA
Control of Customer-Supplied Product			X	MA
Product Identification and Traceability	X			
Process Control	X		X	
Inspection and Testing	X	X	X	
Control of Inspection, Measuring, and Test Equipment	X			
Inspection and Test Status	X	X	X	
Control of Non-Conforming Material	X		X	
Corrective and Preventive Action	X	X	X	
Handling, Storage, Packaging, Preservation, and Delivery	X			
Control of Quality Records	X	X	X	
Internal Quality Audits			X	
Training			X	
Servicing			MAYBE	
Statistical Techniques			MAYBE	

Audit Protocol - Audit Do's

- Know what our Quality Policy means
- Know how you can help meet the quality system goals
- Be professional, friendly, courteous
- Know that what you do makes a difference
- Answer questions truthfully
- Take time to think about answers before giving them

Audit Do's (continued)

- If you don't know the answer, direct the auditor to your supervisor (or Team Lead)
- Ask for clarification if you don't understand the question
- Be as direct as possible when answering the questions
- Make sure you understand any problems the auditor finds

Audit Do's (continued)

- Know what procedures govern the work you are doing
- Know how to ensure you have the current version of your procedures
- Follow procedures and work instructions rigorously
- Make sure you work area is neat and orderly

Audit Protocol - Audit Don’ts

- Criticize coworkers, management or the organization
- Act like the auditor is wasting your time
- Think that your answers won’t count
- Lead the auditor to problems
- Be afraid to say “I don’t know, but I’ll find out”
- Guess at answers

Audit Don’ts (continued)

- Try to bluff through an answer
- Volunteer information not asked for
- Argue with the auditor
- Say “I don’t follow procedures because…,” “I don’t have time…,” “It can’t be done that way”

Audit Don’ts (continued)

- Show the auditor out of date copies of the procedures
- Show the auditor very old records

SO 9001 to ISC Terminology Translation

ISO 9001 Terminology	ISC Translation
Quality Plan for a product	Product Plan
Design Plan	Product Plan (Section 4- Technical Approach)
Verification Plan	Unit/Build Test Plan (ensure design output meets design input requirements
Validation Plan	Acceptance Test Plan (ensure product conforms to user needs and requirer
Quality System	GSFC QMS (know how to bring it up online)
Quality Policy	to provide world class products that meet or exceed customer requirements
Supplier	in ISO terms, WE are the supplier
Customer	person to whom you are supplying the product
Contract Review	Customer Agreement
Subcontractors	contractors from whom we purchase things
Test Equipment (software)	includes test software
Product Identification	for hardware or software (e.g., build/version # for software, part/lot/run # for
Corrective Action	how we fix the product's immediate problem
Preventive Action	how we prevent the problem from reoccurring
Management Representative	Richard Day

GSFC Audit Schedules

- Internal Audits will be occurring continuously throughout the year
- Official External Audits occur twice yearly
  -Currently in February and August

What now?

- This is the only formal presentation on ISO 9001 that you are required to attend
- Code 580 ISO Representatives in each branch are here to help you **CHECK** what you are doing
- It is **YOUR** responsibility to bring **YOUR** activities in compliance with ISO 9001/ QMS requirements, and within GSFC schedules

so.....

- You must figure out what you need to do to be compliant
- We suggest starting by looking at the documents listed in the “pyramid”.

Backup Slides